



# Comparison of generic and condition-specific oral health-related quality of life instruments in patients with oral submucous fibrosis

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## Abstract

**Purpose** With the growing interest in health economics, there is a demand for best valid instrument to assess quality of life (QoL) in patients with oral submucous fibrosis (OSF). The objective of this study was to compare the convergent and discriminative properties of the condition-specific OHRQoL-OSF and generic OHIP-14 in OSF patients.

**Methods** The OHRQoL-OSF and OHIP-14 instruments were administered concurrently to 300 clinically diagnosed OSF patients. Analysis of both the instruments was carried out by using descriptive statistics. The internal consistency and reproducibility of the instruments were assessed using Cronbach's alpha and intra-class correlation coefficient respectively. The convergent and discriminative validity were then determined and compared.

**Results** The OHRQoL-OSF and OHIP-14 exhibited good psychometric properties for internal consistency (Cronbach's alpha > 0.88) and reproducibility (ICC > 0.85). A positive associations were observed between both the instruments, but a high prevalence of patients with no impact was noted using the OHIP-14. Both the instruments were able to discriminate between patients with different clinical stages of OSF, but OHRQoL-OSF was more responsive in the early stages of OSF. The OHRQoL-OSF demonstrated greater sensitivity for 'discomfort and functional impairment'.

**Conclusions** The condition-specific OHRQoL-OSF identified OSF patients with impaired oral health-related QoL more easily with greater discriminative properties. To better understand patient reported experiences in OSF, these results may guide the choice of instrument in future researches and surveys.

**Keywords** Quality of life · Oral health · Oral submucous fibrosis · OHRQoL-OSF · OHIP-14

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## Introduction

Quality of life (QoL) is a vital and often required health outcome measure that is relevant to the patients care. The oral health-related QoL (OHRQoL) is a requisite part of general health and has been proclaimed by the World Health Organization as an essential component of the global oral health program [1]. The OHRQoL is a multi-dimensional construct including subjective evaluation of the individual's oral health, functional wellness, emotional wellness, expectations and satisfaction with respect to oral health and self-esteem [2, 3]. A healthy oral cavity empowers an individual to perform routine activities without any physical and psycho-social limitations [4]. However, any disturbance in a comfortable and functional oral cavity may result in decreased self-confidence and social interaction of the affected individual [5], compromising the QoL. Therefore, assessment of the impact of oral diseases on QoL should be part of routine practice with thorough clinical examination to recognize oral health care needs of the patients [6]. Moreover, determining proper treatment protocols and measuring outcomes based on patient reported experiences is definitely changing the tradition of clinical practice, surveys and research in recent years [7].

Oral submucous fibrosis (OSF) is a chronic progressive disease of the oral mucosa with malignant potential of 7–30% [8]. OSF patients are severely affected with significant health-related (HR) symptoms including limited mouth opening, burning sensation in the mouth, frequent ulcerations, psycho-social impairment, etc. [9]. Limited studies in the past have revealed significant influence of OSF on QoL of affected individuals [10–14]. In addition, worsening of QoL is associated with advanced stages of OSF [13, 14]. However, it could be possible that the results of these studies might lack accuracy as they have employed different generic questionnaires (EQ-5D-3 L, EORTC's QLQC, OHIP-14 and OPMDQoL) that may not be completely appropriate or sensitive for OSF [15]. A condition-specific 'OHRQoL-OSF' instrument was recently developed and validated in OSF patients [16].

It could be possible that condition-specific instruments perform better than generic measures as they assess the impact of a particular condition on daily activities and life quality of a diseased person [17]. Researchers have been continuously focusing on improving the QoL of affected individuals. Therefore, it is foremost prerequisite to employ the best available QoL instrument for use in OSF. Keeping this in mind, the present study was designed to find out whether a condition-specific OHRQoL-OSF is more discriminative and responsive than generic OHIP-14.

## Methods

### Study population

The present study employed a cross-sectional design. Patients clinically diagnosed with OSF without any systemic disorder were invited to participate. The OSF cases were categorized based on the following clinical criteria: intolerance to hot and spicy foods, pale-looking oral mucosa, palpable fibrotic bands in the oral cavity and chronic progressive reduction in mouth opening [18, 19]. All the participants were required to be above 18 years of age and capable of reading and understanding the questionnaires on their own. However, patients undergoing treatment for OSF were excluded as most of them do not present QoL related problems associated with the disease. A total of 315 OSF patients who were possible candidates for inclusion in the study were selected by convenience sampling method from the outdoor department from December 2017 to June 2018. Fifteen patients were excluded as they refused to participate in the study due to disinterest and time constraints. Finally, 300 patients were recruited in the study. A thorough clinical examination of each patient was performed by a well-trained oral physician (having experience of more than 10 years in the field) and the inter-incisal mouth opening was measured using digital vernier caliper. All the patients were divided into four groups based on the range of mouth opening as stage I (35–40 mm), stage II (30–34 mm), stage III (20–29 mm), and stage IV (< 20 mm) as explained by Lai et al. [20]. All the participants provided written informed consent. Ethics approval was obtained from the Institutional ethics committee of Datta Meghe institute of medical sciences, Wardha, India (Ref no. DMIMS (DU)/IEC/2017-18/6900, dated 16/12/2017). The current study is the continuation of our previous study which evaluated the impacts of OSF on OHRQoL [21].

### Study instruments

In the present study, OHRQoL-OSF and OHIP-14 instruments were used to determine the impacts of OSF on QoL. For this, the OHIP-14 questionnaire was translated into Marathi (native language of the study participants) by standard forward and backward translation technique [22]. This involved translation of English OHIP-14 into Marathi by two independent translators who were experts in both the languages, who then discussed and produced a consensus Marathi version. Back translation was performed by two other translators independently who were not a part of the study but were expert in both the languages

and had never seen the original version. All versions were consolidated to develop a final questionnaire by all the translators. The resultant Marathi questionnaire was then pilot tested on ten patients for face and content validity to optimize the intelligibility of each item. Before administering, all the required changes were executed to improve the comprehensiveness of OHIP-14.

The OHRQoL-OSF is a 17-item condition-specific instrument for OSF with four dimensions (discomfort and functional impairment, psychological wellness, physical wellness and social wellness). This instrument measures responses of patients using a four-point Likert scale from 0 to 3 with “Not at all = 0” and “Very much = 3.” The sum of scores of all the items represents the total OHRQoL-OSF score [16]. The OHIP-14 is a generic instrument with seven dimensions (functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap). Responses for each item are coded as ‘very often’ (scoring 4), ‘fairly often’ (3), ‘occasionally’ (2), ‘hardly ever’ (1) or ‘never’ (0) [23]. A higher total score indicates a poor QoL, while a lower score denotes better QoL for both OHRQoL-OSF and OHIP-14. Moreover, the individual subscale score finds out the impacts of a condition on a particular aspect of affected individuals.

### Patient-reported perception on oral health and treatment

The perceived oral health is a subjective measure of individual’s perception of his/her oral health. The commonly used measure is a single-item perceived oral health rating termed “How would you rate your overall oral health?” and categorizes responses into an ordinal scale as “Good”, “Fair” or “Poor”. Similarly, the “self-perceived dental treatment needs” was determined using response categories as “Yes” or “No”. Finally, the outcome for “perceived oral health satisfaction” was determined using response categories as “Yes” or “No”. These standardized measures are commonly used in the literature [10, 24], and same has been used in the present study.

### Data collection

All the participants were personally interviewed by the principal author, and data were collected from clinical examination, OHIP-14 and OHRQoL-OSF questionnaires. In addition, the self-perceived oral health data were obtained from patient-reported perception on oral health and treatment.

### Data analysis

The socio-demographic data were analyzed through descriptive statistics. Analysis of the OHRQoL-OSF and OHIP-14

instruments was also carried out by using the same descriptive statistics. Reliability of the OHRQoL-OSF and OHIP-14 instruments was evaluated by internal consistency using the Cronbach’s alpha coefficient test. To assess test–retest reliability, both the questionnaires were administered to the 15 patients 15 days after first administration who revisited the same department for follow-up treatment. Test–retest reliability was tested by intra-class correlation coefficient (ICC) with 95% confidence interval. Cronbach’s alpha value of 0.70 or greater was considered to be acceptable [25]. Since no gold standard exists for OHRQoL indices, the validation process relies on assessment of concurrent validity against a proxy measure of a similar concept. Pearson’s correlation coefficient was used to check the association between the OHRQoL-OSF and OHIP-14. The concurrent validity of both the instruments was assessed by comparing mean scores differences between different subgroups of self-perceived oral health status (SPOHS), perception of need for dental treatment (PNDT) and satisfaction with oral health (SWOH) using the nonparametric Mann–Whitney *U* test as the scores were not normally distributed. The discriminative properties of the OHRQoL-OSF and OHIP-14 were assessed by comparing mean scores differences between different groups with OSF severity. The one-way ANOVA test followed by a Tukey’s post hoc test was used to compare differences between groups.

The data were analyzed using SPSS statistical software, version 22.0. The significance level was set at  $p < 0.05$ .

## Results

### Characteristics of the study patients

Of the 300 recruited patients, 265 were males and 35 were females. The mean age of the participants was 32 ( $\pm 8.60$ ) years (age range 19 to 65 years). All the participants answered items of both the instruments with 100% response rate. The details of the characteristics of the patients are displayed in Table 1.

### Descriptive statistics of the OHRQoL-OSF and OHIP-14

The distribution of the mean subscale scores of OHRQoL-OSF and OHIP-14 is presented in Table 2. Amongst OHRQoL-OSF subscales, ‘discomfort and functional impairment’ ( $6.07 \pm 4.55$ ) was reported to be highly affected aspect followed by ‘psychological wellness’ ( $4.60 \pm 2.84$ ), ‘social wellness’ ( $1.55 \pm 1.47$ ) and ‘physical wellness’ ( $0.84 \pm 1.01$ ). In addition, majority of the participants (91%) had discomfort and functional impairment. 82% participants shown psychological morbidity and more than

**Table 1** Characteristics of the study participants ( $n=300$ )

Parameter	$n$ (%)
Age (years)	
Mean (SD)	32 (8.60)
Range	19–65
Gender	
Male	265 (88.33%)
Female	35 (11.66%)
Educational status	
Post graduates	25 (8.33%)
Graduates	106 (35.33%)
Non graduate 10th pass	127 (42.33%)
Non matric	42 (14.00%)
Employment status	
Employed	240 (80.00%)
Unemployed	35 (11.66%)
Retired	25 (8.33%)
Occupational status	
Higher	48 (16.00%)
Intermediate	66 (22.00%)
Lower	186 (62.00%)
Socioeconomic status	
High	34 (11.33%)
Middle	70 (23.33%)
Low	196 (65.33%)
Clinical stages of OSF	
Stage IV	69 (23.00%)
Stage III	75 (25.00%)
Stage II	75 (25.00%)
Stage I	81 (27.00%)

*SD* standard deviation, *OSF* oral submucous fibrosis

half (55.66%) had experienced disturbed social interaction. Within OHRQoL-OSF instrument, the limited mouth opening (76.56%) and burning sensation in the mouth (68.43%) were highly prevalent impacts, whereas ‘need for more rest’ was least (15.12%) reported by the participants.

Of the seven subscales of OHIP-14, ‘physical pain’ ( $4.13 \pm 3.25$ ) was commonly affected domain followed by psychological discomfort ( $2.89 \pm 1.63$ ) and functional limitations ( $2.05 \pm 1.45$ ) (Table 2). More than half of patients (58.33%) reported ‘physical pain’. Ninety (30.00%) patients reported psychological discomfort and 84 (28.00%) had functional limitations. Within OHIP-14 instrument, majority of the participants (61.23%) were ‘uncomfortable while eating’. Impacts such as ‘totally unable to function’ and ‘difficulty in doing jobs’ were mentioned by only few participants (5.36%).

### Reliability and reproducibility of the OHRQoL-OSF and OHIP-14

The overall internal reliability of the OHRQoL-OSF and OHIP-14 as assessed by its Cronbach’s alpha value was 0.900 and 0.890, respectively. A good internal consistency was reported for all the domains of the both the instruments. Repeated administrations exhibited ICC of 0.96 (95% confidence interval 0.91–0.97) and 0.91 (95% confidence interval 0.86–0.93) for OHRQoL-OSF and OHIP-14, respectively, with satisfactory reliability for all the domains.

### Concurrent validity

The overall scores of OHRQoL-OSF and OHIP-14 were significantly positively associated with participant’s self-perceived oral health status, level of satisfaction with their

**Table 2** Score distribution of the OHRQoL-OSF and OHIP-14 instruments

Instrument	Number of items	Mean $\pm$ SD	Range	Cronbach’s alpha
OHRQoL-OSF				0.900
Discomfort and functional impairment	9	$6.07 \pm 4.55$	1–19	0.898
Psychological wellness	4	$4.60 \pm 2.84$	0–11	0.846
Physical wellness	2	$0.84 \pm 1.01$	0–4	0.860
Social wellness	2	$1.55 \pm 1.47$	0–4	0.854
OHIP-14				0.890
Functional limitations	2	$2.05 \pm 1.45$	0–4	0.860
Physical pain	2	$4.13 \pm 3.25$	0–7	0.888
Psychological discomfort	2	$2.89 \pm 1.63$	0–6	0.878
Physical disability	2	$1.63 \pm 1.25$	0–3	0.862
Psychological disability	2	$1.75 \pm 1.01$	0–3	0.880
Social disability	2	$1.26 \pm 1.11$	0–3	0.849
Handicap	2	$0.35 \pm 1.25$	0–2	0.729

*SD* standard deviation

**Table 3** Concurrent validity of OHRQoL-OSF and OHIP-14

Instrument	<i>n</i>	Mean ± SD	Mann–Whitney <i>U</i> test ( <i>p</i> value)
<b>OHRQoL-OSF</b>			
SPOHS			
Good (A)	47	5.17 ± 3.60	A < B ( <i>p</i> < 0.001)
Fair (B)	151	10.45 ± 7.55	B < C ( <i>p</i> < 0.001)
Poor (C)	102	21.21 ± 6.74	
PNDT			
Yes	184	22.82 ± 5.31	<i>p</i> < 0.001
No	116	7.26 ± 4.67	
SWOH			
Yes	143	5.18 ± 2.71	<i>p</i> < 0.001
No	157	20.66 ± 5.93	
<b>OHIP-14</b>			
SPOHS			
Good (A)	47	5.19 ± 3.97	A < B ( <i>p</i> < 0.001)
Fair (B)	151	12.04 ± 7.16	B < C ( <i>p</i> < 0.001)
Poor (C)	102	20.89 ± 6.56	
PNDT			
Yes	184	22.65 ± 5.56	<i>p</i> < 0.001
No	116	8.51 ± 4.69	
SWOH			
Yes	143	6.57 ± 3.20	<i>p</i> < 0.001
No	157	20.72 ± 5.87	

SPOHS self-perceived oral health status, PNDT perception of need for dental treatment, SWOH satisfaction with oral health, SD standard deviation

oral health and the perception of need for dental treatment (Table 3).

**Discriminant validity**

A statistically significant difference in the mean total scores of OHRQoL-OSF and OHIP-14 was observed when compared among four groups of OSF severity (Table 4). For OHRQoL-OSF, higher mean score was noticed for stage

IV OSF patients (25.40 ± 3.97) as compared to stages III (15.73 ± 2.21), II (7.18 ± 1.51) and I (3.01 ± 1.92) patients (*p* < 0.001). Similarly, OHIP-14 scores showed better QoL in stage I OSF patients (3.53 ± 0.79) than those with stages II (5.44 ± 1.75), III (16.36 ± 2.52) and IV (24.92 ± 4.85) OSF. However, it should be noted that the mean total scores obtained by OHIP-14 between stages I and II OSF were statistically insignificant (*p* = 0.125). Therefore, it can be said that OHRQoL-OSF has the better ability to differentiate between patients with initial stages of OSF than OHIP-14.

**OSF severity and QoL indices**

The severity of OSF was correlated positively with the overall OHRQoL-OSF and OHIP-14 scores. The mean total scores of both the instruments have shown an increasing trend with the advancement of OSF severity. Amongst dimensions of both the instruments, discomfort & functional impairment (0.930) and psychological wellness (0.860) of OHRQoL-OSF and functional limitations (0.725), physical pain (0.875), and psychological discomfort (0.715) of OHIP-14 demonstrated strong positive association with OSF severity whereas other scales of both the instruments had a weak positive association.

**Discussion**

The present study was designed to evaluate and compare psychometric properties of the OHRQoL-OSF and OHIP-14 in OSF patients. This is the first study to compare condition-specific and generic QoL scores of OSF patients. Both OHRQoL-OSF and OHIP-14 try to address basic health dimensions including functioning, psychological, physical and social aspects. However, each instrument assesses the topic areas covered from different perspectives. OHRQoL-OSF is quite comprehensive and highly specific in terms of various dimensions related to OSF. In contrast, OHIP-14 has a much broader design with multiple dimensions, thus

**Table 4** Discriminant validity of OHRQoL-OSF and OHIP-14 according to severity of OSF

Instruments	OSF severity	<i>n</i>	Mean ± SD	One-way ANOVA		Tukey’s post hoc test ( <i>p</i> value)
				<i>F</i> -test value	Overall <i>p</i> value	
OHRQoL-OSF	Stage I (A)	69	3.01 ± 1.92	1077.728	<i>p</i> < 0.001)	A < B ( <i>p</i> < 0.001)
	Stage II (B)	75	7.18 ± 1.51			B < C ( <i>p</i> < 0.001)
	Stage III (C)	75	15.73 ± 2.21			C < D ( <i>p</i> < 0.001)
	Stage IV (D)	81	25.40 ± 3.97			
OHIP-14	Stage I (A)	69	3.53 ± 0.79	633.508	<i>p</i> < 0.001)	A < B ( <i>p</i> = 0.125)
	Stage II (B)	75	5.44 ± 1.75			B < C ( <i>p</i> < 0.001)
	Stage III (C)	75	16.36 ± 2.52			C < D ( <i>p</i> = 0.001)
	Stage IV (D)	81	24.92 ± 4.85			

ANOVA analysis of variance, SD standard deviation, OSF oral submucous fibrosis

making it a generalized and non-specific or generic type of questionnaire for OSF patients. Therefore, OHRQoL-OSF appears to cover health status among OSF patients quite well. The findings of the present study support previous research which suggested that the condition-specific instruments related to oral health are more sensitive as they summarize number of symptoms related to particular health concerns and thus allow for better measurement of QoL than generic instruments [26, 27].

OHRQoL-OSF and OHIP-14 exhibited good reliability, reproducibility and construct validity for evaluation of OHRQoL. Both the instruments have detected participants with impaired oral health and its impacts on QoL. For OHRQoL-OSF, we reported limited mouth opening and burning sensation in the mouth as highly prevalent impacts of OSF. On the contrary, uncomfortable in eating foods was experienced by majority of the participants amongst OHIP-14 items. Our findings are in accordance with the previous studies [10, 12, 13, 19]. It was evident that both the instruments have related dimensions but quantify functioning, psychological, social and physical relations somewhat differently. As far as OSF is concerned, factors attributing to these findings may include different concepts of oral health, different scoring methods and different patterns of formulating oral health items. The OHRQoL-OSF address questions regarding oral health and problems that are directly related to OSF specifically. However, OHIP-14 questions ask patients about general overall oral health. For example, OHRQoL-OSF ask respondents about ‘difficulty in complete mouth opening’, ‘burning sensation in the mouth’, ‘frequent ulcerations in the mouth’, ‘loss of hearing in recent time’, etc. which altogether are the unique characteristics of OSF, whereas OHIP-14 does not include items related to these major OSF findings. Though some of the items related to psychological issues mentioned in both the instruments are similar, the stress related to the precancerous nature of OSF and its progression to oral cancer is addressed to the patients in OHRQoL-OSF instrument.

Discriminant validity is an important characteristic of the HRQoL instruments. In the present study, both the tested instruments showed different discriminant properties. It was evident that OHRQoL-OSF was more discriminant and identified participants with different impacts of OSF on their QoL more easily. The lowest overall OHRQoL-OSF scores indicating better QoL were reported in stage I OSF patients as compared to patients in other comparison groups ( $p < 0.001$ ). The findings of the present study support previous studies which have shown that OSF patients with advanced stages appear to experience greater oral and general health challenges than those with early stages [10, 13]. Moreover, individual subscale scores of OHRQoL-OSF were observed to be increased with increasing severity of OSF. In the present study, stage IV OSF patients demonstrated higher

effects on all four subscales of OHRQoL-OSF with highly significant impacts on discomfort & functional impairment and psychological wellness. These results are consistent with reports of our previous studies [9, 19]. Similarly, for OHIP-14, we reported higher scores in stage IV OSF patients than in those in other groups ( $p < 0.001$ ). However, statistically insignificant differences were found on comparing the overall and subscales scores of OHIP-14 among stage I and II patients. We believe that identification of OSF patients in this early stages is very crucial. Administration of appropriate treatment in conjunction with patient counselling about habit cessation during this stage is definitely helpful to halt the OSF progression. This may reduce further consequent impacts of OSF on QoL of affected individuals and the cancer burden. The comparison of the health status profiles obtained from both the instruments showed greatest difference in functioning dimension. Also, the social and psychological dimensions of OHRQoL-OSF and OHIP-14 denoted differences, but the scores were not significant.

Despite the availability of numerous instruments to measure OHRQoL in different oral health disparities, it is unclear which instrument performs best in different disease states. In the present study, OHIP-14 was used to compare with the condition-specific OHRQoL-OSF. The OHIP-14 is one of the most popular, internationally spread instrument, available in several languages and widely used in past studies [10, 12, 28]. The OHRQoL-OSF and OHIP-14 address relatively similar dimensions, but have differences in their item contents. This can affect their potential to identify QoL outcomes. The OHRQoL-OSF explores functional impairments and discomfort that are seen from the early stage and frequently caused effects of OSF. However, OHIP-14 focuses more on psychological and social discomforts which are relatively less severe impacts of OSF and commonly reported in moderately advanced and advanced stages. We further noticed that OHIP-14 contains only two items to address functional limitations in contrast to nine items of OHRQoL-OSF. Considering the effects of OSF on oral tissues in early to advanced stages, we believe that coverage of functional limitations by OHIP-14 may be too limited to find out different types of functional impairments experienced by OSF patients. This might be the reason for relatively high proportion of patients with no impacts with OHIP-14 especially in the stage I & II OSF. Thus, it could be possible that condition-specific instruments like OHRQoL-OSF may be more sensitive to functioning & discomfort issues that OSF patients consider important than generic instruments. In the present study, both the instruments were positively correlated with self-perceived oral health status, perception of their satisfaction with their oral health and their need for dental treatment. Majority of patients with the stage III and IV OSF reported unsatisfied oral health status and had high dental treatment needs.

We believe that the findings of the current study must be interpreted with caution as the scores obtained by both the instruments were actually the patient reported outcomes and experiences which quantify their QoL. Few limitations of the study include small population studied with a homogenous demographic distribution. The generalization of the results of this study may be affected by patient characteristics. One obvious limitation is the cross-sectional design of the study. We have not evaluated the responsiveness of two tested QoL instruments to the change in patients' clinical status.

Concluding, in general the generic OHIP-14 and condition-specific OHRQoL-OSF instruments exhibited good psychometric properties in determination of OHRQoL in OSF patients, but latter identified more easily patients with impacts of OSF. In addition, OHRQoL-OSF was more discriminant and better to find out discomfort and functional issues related to oral cavity. The dimensions of both the instruments are relatively similar but have different item contents. We recommend that while choosing among available HRQoL instruments, researchers should not focus simply on the names of the instruments but more importance should be given to the content and structure of the each item. Future studies with larger population and in different cultural and language adaptations are warranted to determine the usefulness and application of these instruments in cost/utility analyses among OSF patients.

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### Compliance with ethical standards

**Conflict of interest** All authors declare that they have no conflicts of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with ethical standards of the Institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

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